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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,584	10/18/2004	William Bedingham	57436US005	5247

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EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,584	BEDINGHAM, WILLIAM	
	Examiner	Art Unit	
	Dwayne K. Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Beecham (5,876,926). Beecham teaches a method, apparatus, and system for verification of human medical data. The method includes the steps of collecting a sample, sealing the sample, shipping the sample to a processing facility, processing the sample, and communicating the results to the user. Beecham teaches a wide variety of testing methods. One embodiment of their invention which is most relevant to the instant claims is recited in column 12, line 60 through column 13, line 35 and details the collection and analysis of a hair sample. The hair sample is collected and sealed into sample container in the presence of the donor and a representative of the testing facility or the entity requesting the test. The sample is then sent to a lab for testing. The results of the testing on the hair sample are then supplied via database where the data on the sample is stored until it can be accessed by either the donor or the entity requesting the sample. Beecham

also teaches the collection of urine, breath, oral, blood, and fingernail samples (column 15). Beecham discloses genetic analysis on biological samples in column 5, lines 28-34.

3. Claims 1-5, 7, 8, 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Brem (6,509,187). Brem teaches a method and device for the preparation of tissue sample for genetic analysis. The method is disclosed in column 5, lines 15-67. In this passage, Brem recites loading the sample material into the container, sealing the container, shipping the container and then performing genetic analysis of the samples. Communication of the results to the user is disclosed in column 7 and Figure 4. Brem details reagent materials for use in the collection container in claim 1. Brem teaches DNA footprinting and PCR analysis of the samples in column 7 and column 8.

4. Claims 1, 8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Morris et al. (6,548,822). Morris teaches a method of performing analytical services. The method is disclosed in column 6 (claim 1 also) and includes the steps of supplying the sample container, placing the sample in the container and closing it, returning the sample to the processing facility for processing, and then notifying the user of the results.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (5,876,926) or Brem (6,509,187). Beecham or Brem teach every element of claim 9 except for returning the sample processing device back to the user. It would have been obvious to one of ordinary skill in the art to return the sample container to the user, however. One would return the sample container to the user so it could be used to collect more samples.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (5,876,926) in view of Koster (5,691,141). Beecham teaches every element of claim 6 except for Sanger sequencing. Beecham teaches genetic analysis but does not

specifically recite Sanger sequencing. Koster teaches DNA sequencing using mass spectrometry. The sequencing is done as a Sanger sequencing, but does not involve any of the electrophoretic separation steps. This saves time and allows for a higher throughput of samples. It would have been obvious to combine the method of Koster for DNA analysis with the analysis method of Beecham. One would use the method of Koster in order to sequence the genetic material without the need for electrophoretic separation.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (5,876,926) in view of Pekko (3,631,637). Beecham teaches every element of claims 12 and 13 except for the tamper proof label. Beecham merely teaches labeling the sample container. Pekko teaches a tamper free label comprised of two pressure sensitive layers. The label is placed on a substrate and then cannot be removed without leaving a portion one of the layers behind when removing the label (Abstract, Figures 1-3). It would have been obvious to one of ordinary skill in the art to combine the tamper proof label from Pekko with the method of Beecham. One would use the label of Pekko on the sample collector of Beecham in order to determine if the label has been removed from the sample container.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schultz, Jr. (4,180,929) and Ewan (4,998,666) teach tamper

indicating seals. Guirguis (6,352,863) teaches an assay device. Cranley et al. (6,609,068) and Gotfried (6,697,732) teach systems for testing samples and then providing the results to the user from a database.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
October 31, 2005

Jill Warden
Supervisory Patent Examiner
Technology Center 1700